

Complete Summary

GUIDELINE TITLE

Supplemental recommendations on adverse events following smallpox vaccine in the pre-event vaccination program: recommendations of the Advisory Committee on Immunization Practices.

BIBLIOGRAPHIC SOURCE(S)

Notice to readers: supplemental recommendations on adverse events following smallpox vaccine in the pre-event vaccination program: Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2003 Apr 4;52(13):282-4. [5 references]

COMPLETE SUMMARY CONTENT

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 INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
 CATEGORIES
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SCOPE

DISEASE/CONDITION(S)

- Myocarditis/pericarditis related to smallpox vaccination
- Cardiac ischemic events related to smallpox vaccination

GUIDELINE CATEGORY

Evaluation
 Screening

CLINICAL SPECIALTY

Infectious Diseases
 Internal Medicine
 Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations about medical screening of potential vaccinees and follow-up of persons with cardiovascular risk factors after vaccination
- To supplement recommendations previously issued by the Advisory Committee on Immunization Practices (ACIP)

TARGET POPULATION

Candidates for pre-event smallpox vaccination program

INTERVENTIONS AND PRACTICES CONSIDERED

Screening Related to Smallpox Vaccination

1. Prevaccination screening forms
2. Verbal screening for cardiac risk factors
3. Review cardiac history
4. Patient education regarding potential complications

MAJOR OUTCOMES CONSIDERED

- Number of cases of myopericarditis among military vaccinees
- Number of cardiac ischemic events among civilians after smallpox vaccination
- Time from vaccination to onset of symptoms
- Mortality due to cardiac disease following vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Patient Registry Data
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- The Advisory Committee on Immunization Practices (ACIP) recommends that persons be excluded from the pre-event smallpox vaccination program who have known underlying heart disease, with or without symptoms, or who have three or more known major cardiac risk factors (i.e., hypertension, diabetes, hypercholesterolemia, heart disease at age 50 years in a first-degree relative, and smoking).

- ACIP supported including these risk factors in prevaccination education materials so that potential vaccinees can evaluate their risk status, if they have concerns, with their personal physician before reporting for vaccination; at the vaccination clinic, verbal screening for known risk factors is recommended. In response to these recommendations, prevaccination screening forms and other materials have been revised; these materials have been provided to state health departments and are available at: www.bt.cdc.gov/agent/smallpox.
- ACIP did not recommend special medical follow-up for persons with cardiovascular risk factors who have been vaccinated. Persons with risk factors or known atherosclerotic coronary artery disease should be cared for by their physicians in accordance with standard guidelines for treatment and control of these conditions, such as those issued by the National Cholesterol Education Program Expert Panel and other expert groups (Expert Panel on Detection, Evaluation, and Treatment of High Blood Pressure in Adults, 2001).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved screening for cardiac disease and risk factors among potential vaccinees
- Decreased cardiac-related morbidity and mortality in vaccinees

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In response to these recommendations, prevaccination screening forms and other materials have been revised; these materials have been provided to state health departments and are available at: www.bt.cdc.gov/agent/smallpox.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Apr 4

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#).

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

Additional information regarding smallpox preparation and response activities is available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#).

See also the following related guidelines:

- Centers for Disease Control and Prevention. Recommendations for using smallpox vaccine in a pre-event vaccination program. Supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Dispatch 2003 Feb 26;52(Dispatch):1-16. See the [National Guideline Clearinghouse \(NGC\) summary](#).
- Centers for Disease Control and Prevention. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. MMWR Recomm Rep 2001 Jun 22;50(RR-10):1-25, CE1-7. See the [NGC summary](#).

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on Apr 14, 2003. It was not verified by the guideline developer.

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